DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 2004

Ms. Daisy P. Sin, MT
Synovis Surgical Innovations
2575 university Avenue W.
St. Paul., Minnesota 55114

Re: K040163
Trade/Device Name: Microvascular Anastomotic Coupler
Regulatory Class: unclassified
Product Code: MVR
Dated: January 23, 2004
Received: January 26, 2004

Dear Ms. Sin:

This letter corrects our substantially equivalent letter of April 7, 2004 regarding the Indications for Use of your device.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part

807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040163

Device Name: Microvascular Anastomotic COUPLER

Indications for Use:

The Microvascular Anastomotic COUPLER is to be used in the anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040163

APR 1 6 2004

K040163

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:
Synovis™ Micro Companies Alliance, Inc.
A Subsidiary of Synovis Life Technologies, Inc.
439 Industrial Lane
Birmingham, AL 35211-4464 USA
FDA Registration #: 1062741

Date Prepared: April 6, 2004

Contact Person:
Daisy P. Sin, MT (ASCP), RAC (RAPS)
Synovis Surgical Innovations,
A Division of Synovis Life Technologies, Inc.
2575 University Ave. W.
St. Paul, MN 55114
651-796-7399, 651-603-5203 or 1-800-225-4018
651-796-7499 (Fax) or 651-603-5211 (Fax)

Device Trade Name: To be determined

Common Name: Microvascular Anstomotic Coupler

Predicate Device: ~~GEM~~ Microvascular Anastomotic COUPLER; K861985

Device Description: The device is a sterile (gamma irradiation), single-use, implantable pair of rings molded out of high density polyethylene with six stainless steel pins on each of the ring. A probe-holder feature is molded on each of the paired rings to be a point of attachment for a sensor/probe at the site of anastomosis.

Indications for Use: The device is for use in the anastomosis of veins and arteries normally encountered in microsurgical procedures.

Technological Comparison: The proposed device has the same technological characteristics as the predicate device.

Summary: The device is substantially equivalent to the predicate device with respect to biocompatibility, manufacturing process, product performance, sterilization, shelf life, packaging, and safety and efficacy.